

**PATENT/Docket No. PC25496A**  
**Appl. No. 10/767,809**  
**Filing Date: 1/29/2004**

### **AMENDMENTS TO THE CLAIMS**

This listing of claims will replace all prior versions, and listings, of claims in the application:

#### **Listing of Claims:**

1. (Original) A vaccine composition comprising an amount of a *Bordetella bronchiseptica* p68 antigen and an adjuvant effective to protect dogs against *Bordetella bronchiseptica*.
2. (Original) The vaccine composition of claim 1 wherein said *Bordetella bronchiseptica* p68 antigen is produced recombinantly.
3. (Original) The vaccine composition of claim 2 wherein said *Bordetella bronchiseptica* p68 antigen is produced recombinantly in *E. coli*.
4. (Original) The vaccine composition of claim 2 wherein said *Bordetella bronchiseptica* p68 antigen comprises the amino acid sequence as set forth in SEQ ID NO: 1.
5. (Original) The vaccine composition of claim 1 wherein said amount of said *Bordetella bronchiseptica* p68 protein is in the range of 0.5 µg to 1000 µg per dose.
6. (Original) The vaccine composition of claim 1 wherein said adjuvant comprises saponin and a surfactant.
7. (Original) The vaccine composition of claim 6, wherein said saponin is Quil A and said surfactant is cholesterol.
8. (Original) The vaccine composition of claim 7 wherein the amount of Quil A is in the range of 1 to 1000 µg per dose, and the amount of cholesterol is in the range of 1 to 1000 µg per dose.
9. (Original) The vaccine composition of claim 1, wherein said adjuvant comprises aluminum hydroxide.
10. (Original) A vaccine composition comprising an amount of a recombinantly produced *Bordetella bronchiseptica* p68 protein and an adjuvant which comprises Quil A and cholesterol, wherein said amount of the *Bordetella bronchiseptica* p68 protein and the adjuvant is effective to protect dogs against *Bordetella bronchiseptica*.
11. (Original) A method of protecting dogs against *Bordetella bronchiseptica* comprising administering to a dog the vaccine composition of any one of claims 1-10.

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12. (Original) The method of claim 11, wherein said vaccine composition is administered by an intravenous, intranasal, oral, intramuscular or subcutaneous route.
13. (Original) The method of claim 11, wherein said dog is administered twice with said vaccine composition with an interval of about 2-4 weeks between the two administrations.
14. (Withdrawn) A combination vaccine for immunizing dogs against canine pathogens comprising a preparation of an attenuated strain of canine distemper (CD) virus, an attenuated strain of canine adenovirus type 2 (CAV-2), an attenuated strain of canine parainfluenza (CPI) virus and an attenuated strain of canine parvovirus (CPV); an inactivated whole or partial cell preparation of a strain of canine coronavirus (CCV), a *Bordetella bronchiseptica* p68 protein, and an adjuvant.
15. (Withdrawn) The combination vaccine of claim 14, wherein the amount of said attenuated strain of CD virus in said combination vaccine is in the range of  $10^2$  to  $10^9$  TCID<sub>50</sub> per dose.
16. (Withdrawn) The combination vaccine of claim 14, wherein the amount of said attenuated strain of CAV-2 in said combination vaccine is in the range of  $10^2$  to  $10^9$  TCID<sub>50</sub> per dose.
17. (Withdrawn) The combination vaccine of claim 14, wherein the amount of said attenuated strain of CPI virus in said combination vaccine is in the range of  $10^2$  to  $10^9$  TCID<sub>50</sub> per dose.
18. (Withdrawn) The combination vaccine of claim 14, wherein the amount of said attenuated strain of CPV in said combination vaccine is in the range of  $10^2$  to  $10^9$  TCID<sub>50</sub> per dose.
19. (Withdrawn) The combination vaccine of claim 14, wherein the amount of the cell preparation of said strain of CCV in said combination vaccine is at least about 100 relative units per dose .
20. (Withdrawn) The combination vaccine of claim 14, wherein said *Bordetella bronchiseptica* p68 antigen comprises the amino acid sequence as set forth in SEQ ID NO: 1 and is produced recombinantly.
21. (Withdrawn) The combination vaccine of claim 20, wherein said *Bordetella bronchiseptica* p68 antigen is produced recombinantly in *E. coli*.

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22. (Withdrawn) The combination vaccine of claim 20, wherein the amount of said *Bordetella bronchiseptica* p68 protein is in the range of 0.5 µg to 1000 µg per dose.
23. (Withdrawn) The combination vaccine of claim 14 wherein said adjuvant comprises saponin and a surfactant.
24. (Withdrawn) The combination vaccine of claim 23, wherein said saponin is Quil A and said surfactant is cholesterol.
25. (Withdrawn) The combination vaccine of claim 24 wherein the amount of Quil A is in the range of 1 to 1000 µg per dose, and the amount of cholesterol is in the range of 1 to 1000 µg per dose.
26. (Withdrawn) A method for immunizing dogs against canine pathogens comprising administering to a dog the combination vaccine of any one of claims 14-26.
27. (Withdrawn) The method of claim 26, wherein said combination vaccine is administered by an intravenous, intranasal, oral, intramuscular or subcutaneous route.
28. (Withdrawn) The method of claim 26, wherein said dog is administered three times with said combination vaccine with an interval of about 3 weeks between the administrations.
29. (Withdrawn) The combination vaccine of claim 14, further comprising a *Leptospira* cell preparation of at least one of *Leptospira bratislava*, *Leptospira canicola*, *Leptospira grippotyphosa*, *Leptospira icterhaemorrhagiae*, or *Leptospira pomona*.
30. (Withdrawn) The combination vaccine of claim 29, wherein said *Leptospira* cell preparation comprises a cell preparation of *Leptospira bratislava*, *Leptospira canicola*, *Leptospira grippotyphosa*, *Leptospira icterhaemorrhagiae*, and *Leptospira pomona*.
31. (Withdrawn) The combination vaccine of claim 30, wherein the amount of each *Leptospira* strain in the vaccine is in the range of about 200 to 2000 nephelometric units per dose.
32. (Withdrawn) A method of for immunizing dogs against canine pathogens comprising administering to a dog with the combination vaccine of claim 29 or claim 30.
33. (Withdrawn) The method of claim 32, wherein said combination vaccine is administered by an intravenous, intranasal, oral, intramuscular or subcutaneous route.
34. (Withdrawn) The method of claim 32, wherein said dog is administered three times with said combination vaccine with an interval of about 3 weeks between the administrations.

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35. (Withdrawn) A combination vaccine for immunizing dogs against canine pathogens comprising a preparation of an attenuated strain of canine distemper (CD) virus, an attenuated strain of canine adenovirus type 2 (CAV-2), an attenuated strain of canine parainfluenza (CPI) virus and an attenuated strain of canine parvovirus (CPV); a *Bordetella bronchiseptica* p68 protein, a *Leptospira* bacterin which comprises a cell preparation of at least one of *Leptospira bratislava*, *Leptospira canicola*, *Leptospira grippotyphosa*, *Leptospira icterohaemorrhagiae*, or *Leptospira pomona*; and an adjuvant.

36. (Withdrawn) The combination vaccine of claim 35, wherein said *Leptospira* bacterin comprises a cell preparation of *Leptospira canicola* and *Leptospira icterohaemorrhagiae*.

37. (Withdrawn) The combination vaccine of claim 35, wherein said *Leptospira* bacterin comprises a cell preparation of *Leptospira bratislava*, *Leptospira canicola*, *Leptospira grippotyphosa*, *Leptospira icterohaemorrhagiae*, and *Leptospira pomona*.

38. (Withdrawn) The combination vaccine of claim 35, wherein the amount of said attenuated strain of CD virus in said combination vaccine is in the range of  $10^2$  to  $10^9$  TCID<sub>50</sub> per dose.

39. (Withdrawn) The combination vaccine of claim 35, wherein the amount of said attenuated strain of CAV-2 in said combination vaccine is in the range of  $10^2$  to  $10^9$  TCID<sub>50</sub> per dose.

40. (Withdrawn) The combination vaccine of claim 35, wherein the amount of said attenuated strain of CPI virus in said combination vaccine is in the range of  $10^2$  to  $10^9$  TCID<sub>50</sub> per dose.

41. (Withdrawn) The combination vaccine of claim 35, wherein the amount of said attenuated strain of CPV in said combination vaccine is in the range of  $10^2$  to  $10^9$  TCID<sub>50</sub> per dose.

42. (Withdrawn) The combination vaccine of claim 35, wherein said *Bordetella bronchiseptica* p68 antigen comprises the amino acid sequence as set forth in SEQ ID NO: 1 and is produced recombinantly.

43. (Withdrawn) The combination vaccine of claim 42, said *Bordetella bronchiseptica* p68 antigen is produced recombinantly in *E. coli*.

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44. (Withdrawn) The combination vaccine of claim 42, wherein the amount of said *Bordetella bronchiseptica* p68 protein is in the range of 0.5 µg to 1000 µg per dose.
45. (Withdrawn) The combination vaccine of claim 35 wherein said adjuvant comprises saponin and a surfactant.
46. (Withdrawn) The combination vaccine of claim 45, wherein said saponin is Quil A and said surfactant is cholesterol.
47. (Withdrawn) The combination vaccine of claim 46 wherein the amount of Quil A is in the range of 1 to 1000 µg per dose, and the amount of cholesterol is in the range of 1 to 1000 µg per dose.
48. (Withdrawn) A method of for immunizing dogs against canine pathogens comprising administering a dog with the combination vaccine of any one of claims 35-37.
49. (Withdrawn) The method of claim 48, wherein said combination vaccine is administered via an intravenous, intranasal, intramuscular or subcutaneous route.
50. (Withdrawn) The method of claim 48, wherein said dog is administered once with said combination vaccine.
51. (Withdrawn) The method of claim 48, wherein said dog is administered twice with said combination vaccine with an interval of at least about 21 days between the two administrations.